

REMARKS

Reconsideration of this application is respectfully requested.

Claims 1-6, 24-31, and 50-51 are in the application. Claims 1 and 24 have been amended.

In the Official Action, the Examiner rejected claims 1-6 and 24-27 under 35 U.S.C. §102(b) as being anticipated by Sundrehagen (U.S. Patent No. 5,919,708).

Sundrehagen is directed to an assay for glycated blood proteins. The assay evaluates the level of protein glycation to determine a person's control of glucose concentration averaged over a period of time. (column 1, lines 6-7; column 1, lines 20-32) As set forth at column 2, line 45-column 3, line 4, the Sundrehagen method includes, *inter alia*, separating glycated blood protein and corresponding non-glycated blood protein from a sample; contacting the sample with a first signal forming agent; and, optionally, contacting the sample with a second signal forming agent. As set forth at column 4, lines 14-20, the "protein separating step does not require the separation of the total amount of glycated protein and non-glycated protein present in the sample. It is sufficient for only a proportion of both the glycated and non-glycated fractions to be separated as long as the method is appropriately calibrated." Thus, an amount of the protein must be separated from the sample sufficient to evaluate the level of glycation.

Sundrehagen discloses various agents for achieving separation. With reference to column 11, lines 9-65, various precipitating agents are disclosed for separating the target protein from a sample. Bromosulphophthalein-glutathione is disclosed herein as an agent for use in the separating step. (column 11, lines 46-54). Specifically, bromosulphophthalein-glutathione is disclosed as an immobilized ligand.

Separately, bromosulfophthalein (BSP) is disclosed at column 8, lines 5-6 as being an example of an organic dye which is usable as a second signal forming agent. (see, e.g. column 8, line 36 ("Other dyes which may be used as the second signal forming agent . . .")). The BSP is clearly used for a different purpose than the bromosulphophthalein-glutathione. Significantly, there is no disclosure or suggestion in Sundrehagen to have the second signal forming agents immobilized or attached to a support surface, much less to have BSP, in particular, immobilized or attached to a support surface. (see, column 4, lines 30-34, "Consequently, there is no need for the first signal-forming agent to be immobilised since it need not be used as part of a separation system, and indeed it is preferred that it is not immobilised.").

In the Official Action, at pages 6 and 7, the Examiner dealt with Applicant's previous arguments. At page 6, the Examiner stated, "[b]ecause claim 1 uses the open claim language 'comprising' the ligand must only include bromosulfophthalein and does not exclude other compounds from the ligand. Therefore a compound of bromosulfophthalein-glutathione comprises bromosulfophthalein." In response, claims 1 and 24 have been amended to indicate that the ligand consists of BSP or a salt of BSP or an ester of BSP. With the "consisting of" language, the bromosulfophthalein-glutathione is not covered. (see, e.g. MPEP §2111.03 ("The transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim.")).

The Examiner noted at page 7 that the second signal forming dye of BSP "may bind to albumin which is attached to the substrate through an albumin binding ligand." Claims 1 and 24 have been amended to indicate that the ligand is attached "without being exposed to albumin". Thus, the second signal forming agent in Sundrehagen cannot be relied upon as allegedly corresponding to an "attached" ligand.

In addition, there is no disclosure or suggestion in Sundrehagen to use the BSP in the separating step. The only application for the BSP in Sundrehagen is as a second signal forming

agent. Sundrehagen was aware of BSP, but chose not to specify it as a precipitating agent for separation. Rather, only bromosulfophthalein-glutathione is disclosed. One skilled in the art would not be motivated to substitute one for the other. (see, MPEP §2143.01(III) (“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.”). It is respectfully submitted that claims 1-6 and 24-27 are patentable over Sundrehagen.

The Examiner rejected claims 24 and 27-31 under 35 U.S.C. §103(a) as being unpatentable over Pieper et al. (U.S. Published Application No. 2002/0127739) in view of Sundrehagen. The Examiner admitted that “Pieper et al. failed to teach a ligand of bromosulfophthalein” and relied on Sundrehagen for allegedly overcoming this deficiency.

In response, Applicant notes that Sundrehagen does not disclose the use of BSP as recited in claim 24. Rather, as noted above, amended claim 24 is distinguishable from Sundrehagen. The hypothetical combination of Pieper et al. and Sundrehagen would use Pieper et al.’s method with BSP dissolved in a homogeneous solution. Accordingly, the hypothetical combination of Pieper et al. and Sundrehagen does not teach each and every element of claims 24 and 27-31. It is respectfully submitted that claims 24 and 27-31 are patentable over Pieper et al. and Sundrehagen, each taken alone or in combination.

Claim 50 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sundrehagen as applied to claim 1 in view of Matzinger et al. (U.S. Patent No. 6,680,176) and further in view of Shi et al. (U.S. Patent No. 5,919,626). The Examiner admitted that Sundrehagen “failed to teach the ligand attached via an epoxy linkage.”

Claim 50 depends from claim 1. It is respectfully submitted that for the reasons set forth above, claim 50 is also patentable.

Applicant: William Galbraith
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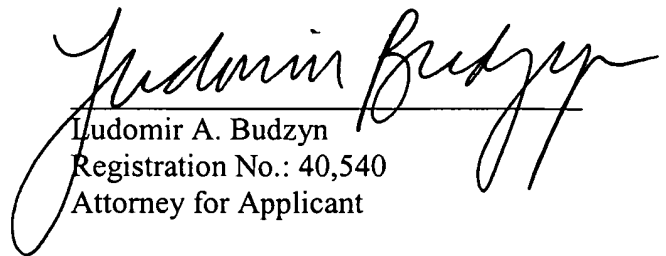
The Examiner rejected claim 51 under 35 U.S.C. §103(a) as being unpatentable over Pieper et al. in view of Sundrehagen as applied to claim 24 in view of Matzinger et al. and further in view of Shi et al.

Claim 51 depends from claim 24. It is respectfully submitted that for the reasons set forth above, claim 51 is also patentable.

Claims 1-6 and 24-31 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-6 and 24-31 of co-pending Application No. 10/922,560. With the amendments herein, it is respectfully submitted that the same invention is no longer claimed in both applications.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

Respectfully submitted,


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